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DOI:

[10.1111/add.14182](https://doi.org/10.1111/add.14182)

*Document Version*

Peer reviewed version

[Link to publication record in King's Research Portal](#)

*Citation for published version (APA):*

Yong, H-H., Borland, R., Cummings, K. M., & Partos, T. (2018). Do predictors of smoking relapse change as a function of duration of abstinence? Findings from the United States, Canada, United Kingdom and Australia. *Addiction*, 113(7), 1295-1304. <https://doi.org/10.1111/add.14182>

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# **Do predictors of smoking relapse change as a function of duration of abstinence? Findings from the United States, Canada, United Kingdom and Australia**

Hua-Hie Yong PhD<sup>1</sup>, Ron Borland PhD<sup>1</sup>, K. Michael Cummings PhD<sup>2</sup>, Timea Partos PhD<sup>3</sup>

1 Nigel Gray Fellowship Group, Cancer Council Victoria, Melbourne, Australia

2 Department of Psychiatry & Behavioral Sciences, Medical University of South Carolina, Charleston, USA

3 Department of Addictions, Institute of Psychiatry, Psychology, and Neuroscience, King's College London, UK

Word count: 4340

Running head: Time-varying effects of smoking relapse predictors

## **Declaration of interests**

Dr. Cummings has received grant funding from Pfizer, Inc. to study the impact of a hospital based tobacco cessation intervention and also has served as an expert witness in litigation filed against the tobacco industry. None of the other authors has any conflict of interest to declare.

Corresponding author: Hua Yong, PhD

615 St Kilda Rd,

Melbourne VIC 3004, Australia

Tel: 61-3-9514-6283

Fax: 61-3-9514-6800

E-mail: hua.yong@cancervic.org.au

## **ABSTRACT**

**Aims** To estimate predictors of time to smoking relapse and test if prediction varied by quit duration.

**Design** Longitudinal cohort data from the International Tobacco Control Four-Country survey with annual follow up collected between 2002 and 2015. Setting Canada, US, UK and Australia.

**Participants** A total of 9,171 eligible adult smokers who made at least one quit attempt over the

study period. Measurements Time to relapse was the main outcome. Predictor variables included pre-quit baseline measures of nicotine dependence, smoking and quitting related motivations, quitting capacity, and social influence, and also two post-quit measures, use of stop-smoking medications and quit duration (1-7 days, 8-14 days, 15-31 days, 1-3 months, 3-6 months, 6-12 months, 1-2 years and 2+ years), along with socio- demographics. Findings All factors were predictive of relapse within the first six months of quitting but only wanting to quit, quit intentions and number of friends who smoke were still predictive of relapse in the 6-12 months period of quitting (hazard ratios [HR]=1.20,  $p=.018$ ; 1.13,  $p=.040$ ; and 1.21,  $p<.001$ , respectively). Number of friends smoking was the only remaining predictor of relapse in the 1-2 years quit period (HR=1.19,  $p=.001$ ) with none predictive beyond the 2 years quit period. Use of stop-smoking medications during quit attempts was negatively related to relapse in the first two weeks of quitting (HR=.71-.84) but positively related to relapse in the 1-6 months quit period (HR=1.29-1.54). Predictive effects of all factors showed significant interaction with quit duration except for perceiving smoking as an important part of life, prematurely stubbing out a cigarette and wanting to quit. Conclusions Among adult smokers in the US, Canada, UK and Australia, factors associated with smoking relapse differ between the early and later stages of a quit attempt suggesting the determinants of relapse change as a function of abstinence duration.

Keywords: smoking relapse, time-varying effects, survival analysis, duration of abstinence

## INTRODUCTION

Tobacco control efforts have been remarkably successful at getting smokers to try to quit (1), but have been far less successful in helping them to maintain abstinence. The most recent Cochrane review concluded again that there is nothing much that prevents longer term relapse from attempts to quit smoking although some behavioural interventions and long term use of a nicotine replacement show promise (2). Most past research has focused on encouraging smokers to make quit attempts. Based on the now well-established understanding that factors associated with making quit attempts are not necessarily the same as those associated with quit maintenance (1, 3), recent efforts have shifted towards understanding what might prevent smoking relapse among those who try. Identified predictors of relapse include nicotine dependence (4), smoking and quitting related motivations (1, 5), low self-efficacy (6), social influences (7) and not using smoking cessation aids (4). It is estimated that even with help around 85% who quit successfully will relapse back to smoking within a year (8) and even after prolonged periods of abstinence, relapse is still possible, underscoring the need to understand not just short and medium term relapse risk but also long-term

risk (9).

The few attempts to theorise the determinants of maintenance have focused on the time it takes to extinguish the habit (overcoming dependence), and on the limits of self-control (e.g., Piasecki et al. (10); Borland (11)). These theories suggest different determinants of relapse as a function of these two factors which relate approximately to the amount of time quit. In our work, we have identified three possible phases of quitting: (1) an initial implementation period which may last several days; (2) then a period of consolidation where there is a restored need for active self-regulation; and (3) finally, a synthesis period where staying quit stops being a primary focal activity, although occasional vigilance is still required as long-term habits develop and old ones extinguish. These distinctions, based on the Context, Executive and Operational Systems (CEOS) theory (11), have been operationalised in the QuitCoach, an automated personalised cessation program (12), which has shown evidence of preventing relapse (13). The use of medication to reduce cravings is theorised to provide a period for new habits to develop but if the medication use is stopped before the new habit is stabilized, then the consolidation period may be prolonged resulting in cessation fatigue when self-control resources are depleted (10) and this may increase relapse rates during the synthesis phase.

Research to date has mostly focused on studying predictors of short, medium and long term relapses separately with no attempt to understand how relapse predictors might vary over the course of quitting (e.g., Caraballo et al (14); Gokbayrak et al (15); Kerr et al (9); Swan et al (16)). Consequently, relatively little attention has been paid to tailoring stop-smoking interventions to the length of time that an individual has been abstinent from smoking. Consistent with the aforementioned theories, there is emerging evidence that the determinants of relapse in the long term are different to those in the short term (17, 18). For example, the Heaviness of Smoking Index (HSI), a well-established behavioural measure of nicotine dependence, has been shown to be predictive of relapse only in the first few weeks of quitting (18) and not beyond. Other predictors of smoking relapse had not been studied before but would be expected to vary by quit duration as well. The CEOS theory would predict that highly dependent smokers who report making a quit attempt with the help of stop-smoking medications (SSM) would have lower odds of relapse in the initial weeks of quitting but once they are off SSM, they may be more vulnerable to relapse. Reported number of friends smoking may not be predictive of relapse in the early days of quitting when smokers concentrate on staying quit but become strongly predictive of relapse once quitting is no longer the focus. A better understanding of how the predictive effects of known predictors of relapse might change over time quit would help inform how best to tailor interventions that are time sensitive.

The present study extends the analysis reported by Yong et al (18) with the aim of

investigating, among adult smokers in the US, Canada, UK and Australia, whether and how the strength of association with time to relapse of known predictors of smoking relapse varied as a function of duration of abstinence. Specifically, the study aimed to (1) estimate the strength of association between the set of factors known to predict relapse and time to relapse; and (2) test whether strength of association with time to relapse for this set of factors, all measured before the target quit attempt except for use of stop-smoking medication which was asked retrospectively in relation to the target quit attempt, varied by duration of abstinence. Differential predictors were examined in periods ranging from the first week to over 2 years post quit. It is hoped that the findings might help identify factors to assist ex-smokers with remaining abstinent for the long term. Apart from expecting HSI to lose its strength of association after around 1 month quit (18), we had no strong predictions, but an expectation that valuing smoking and having smoking embedded in their lifestyle (e.g., having lots of smoking friends) might be more likely to be predictive over longer periods.

## METHODS

### Design

Longitudinal cohort survey with approximately annual follow up conducted between 2002 and 2015.

### Data source and sample

Data come from Waves 1 to 9 of the International Tobacco Control Four Country (ITC-4) survey, a cohort study of broadly representative samples of around 2000 adult smokers per country per wave followed up approximately annually in Australia, Canada, the UK and the US. To maintain the sample size at each subsequent wave, those lost to attrition were replenished using the same sampling procedures as in Wave 1. The broad aim of the ITC-4 was to evaluate the psychosocial and behavioural impact of tobacco control policies on smokers. Full details of the ITC conceptual model and methodology have been published elsewhere (19, 20). Briefly, respondents were recruited into the study as smokers who met the following criteria: aged 18+ years, had smoked at least 100 cigarettes in their lifetime, and smoked at least once in the past 30 days. Participants who subsequently quit smoking were retained in the study. To be eligible for the study, respondents had to be a smoker at the baseline wave (Wave T), to have provided valid data for the selected predictor variables at this wave, and to have made a quit attempt lasting at least 1 day by the next survey wave (Wave T+1), and to have provided outcome data on that attempt either at that wave, or for

those still quit at subsequent waves after the target attempt. The study sample (see Table 1 for sample characteristics) consisted of 9,171 participants who met our inclusion criteria.

## Measures

**Predictor variables:** This set of pre-quit variables was assessed at the most proximal wave prior to quitting and were selected based on their known relationship with relapse (17). They included several measures of nicotine-dependence [Heaviness of Smoking index modified version derived based on square-root transformed cigarettes per day, CPD and natural log transformed time to first cigarette of the day, TTFC (21), perceived difficulty of quitting, and past year failed quit attempts], two measures of smoking functional value (enjoyment and important part of life), measures of quitting-related motivation and capacity (wanting to quit, quit intentions, and quitting self-efficacy), micro-behavioural indicator of health concern about smoking (premature stubbing out) and social influence (number of friends smoking). The question wording along with response option and mean levels (SD) are presented in Table 2.

**Outcome variable:** Time to relapse was the main outcome. At each follow-up, respondents were asked their smoking status. If quit, they were coded as having made a quit attempt since the last survey and were asked how long ago they quit. If smoking, they were asked whether they had tried to quit since the previous wave, and if so, the duration of the quit attempt. For those who made multiple attempts since the previous wave, they were asked the duration of their most recent attempt. For those who were quit at two or more successive waves, their quit duration was computed by adding on the exact inter-wave interval, plus any reported durations within inter-wave intervals. The quit length information was then used to derive time to relapse in days for each individual. Relapse was defined as any quit attempt that ended in failure (i.e., resumed smoking at least monthly) identified at a given follow-up assessment. Because of coding complexity, only one quit attempt (typically the first one) was coded for analysis for participants who made multiple quit attempts over the study period.

**Control variables:** These included age, sex, annual household income, highest level of education, country of residence, and cohort (i.e., year recruited into the study).

## Statistical analysis

All analyses were conducted in Stata 14.1. The association between the set of predictor variables and time to relapse was modelled using survival analysis. Our modelling strategy used a fully parametric approach, parameterised as a proportional hazard model. We modelled the underlying

distribution of time using the Weibull distribution. Given that preliminary analyses indicated that the predictor variables were low to moderately correlated with each other ( $r=.01-.58$ ), we first fitted separate partially adjusted models (model A) for each of the predictors and then, we fitted a fully adjusted model (model B) whereby the full set of predictor variables was entered simultaneously into the model to determine their independent effect on relapse. To test our hypothesis that the effect of some predictors was not constant over time (time-varying coefficient), we fitted interactions between time quit and the set of predictors. To this end, we expanded our dataset into 8 unequal time-intervals (1-7 days, 8-14 days, 15-31 days, 1-3 months, 3-6 months, 6-12 months, 1-2 years and 2+ years) using the `stsplint` command for survival data. The intervals were chosen to reflect the differential changes over time in theorized predictors of relapse, following either a logarithmic or square-root function (22), and also to maximise the number in each time interval, shorter interval at the beginning to reflect the more rapid rate of relapse and progressively longer to correspond to the slower rate as quit attempt progresses over time. Participants were classified into each time interval as follows: all participants were included in the first time interval (i.e., 1-7 days, this cutpoint was chosen because of the long follow-up period of the survey making finer distinctions difficult) and those who survived (i.e., still quit) were included in the next time interval (i.e., 8-14 days) but those who had relapsed were excluded. This was repeated for each subsequent interval for those still quit until they had relapsed or were lost to attrition or were censored at the end of study period. All models controlled for potential confounders such as age, sex, income, education, and country, and also adjusted for any within-cohort clustering using clustered sandwich estimators. We reported hazard ratios (HR) as an index of the strength of the association between predictor variables and time to relapse over the eight intervals of interest. They are interpreted as the effect of a 1 unit change in the predictor variable over the interval of interest on the risk of relapse.

## RESULTS

Over the study period, 9,171 adult smokers who met the study criteria were included in the survival analysis where 31,522 data points were analyzed across the 8 time quit intervals, of which 25,004 were censored (1,966 due to drop-outs) and 6,518 were failures (see Table 1 for details by time quit interval). The overall survival curve is presented in supplementary Figure S1.

Table 3 presents the results from the partially and fully adjusted models showing the association between the set of predictors and relapse at each time quit interval. Measures of nicotine dependence such as HSI and its components (CPD and TTFC) were all significantly associated with relapse in the first 6 months in the partially adjusted model and first 3 months in the fully adjusted

model but not beyond. Their strength of association also diminished over time quit intervals (significant interaction with time quit). Interestingly, while the predictive effect of CPD and TTFC was similar in the partially adjusted model, it differed in the fully adjusted model whereby TTFC was only predictive of relapse in the first week of quitting whereas CPD was predictive up to 3 months. Hard to quit, another measure of dependence, was predictive of relapse in the first 3 months of quitting in the partially adjusted model but in the fully adjusted model, was predictive only in the first week of quitting, and unexpectedly, became protective at the 1-2 year period of quitting.

Enjoyment and important part of life measures showed different patterns of prediction. Partially adjusted model revealed that enjoyment was not predictive of relapse at any of the time quit intervals whereas important part of life was predictive in the first month of quitting. However, the fully adjusted model indicated that enjoyment was a significant predictor within the first 6 months of quitting with evidence of a significant interaction with time quit interval whereas the effect for important part of life measure had now reversed showing, being protective, but only for relapse occurring within 1-2 weeks and 1-3 month period.

Premature stubbing out, a behavioural measure of health concern, was predictive of relapse between 8 days and 3 months of quitting in the partially adjusted model but only within the first month in the fully adjusted model with no significant interaction with time quit interval for either model.

The three measures of quit related motivation (ie., past year failed quit attempts, wanting to quit and quit intentions) all showed quite different patterns of prediction. Partially adjusted model revealed that past year failed quit attempts were predictive of relapse in the first 6 months of quitting with the predictive effect increasing over time (significant by time quit interval interaction). In the fully adjusted model, this measure remained predictive in the first 6 months of quitting except for the second week but the predictive effect no longer differed over the different time periods (by-time quit interval interaction was not significant). Wanting to quit, on the other hand, was predictive of relapse between 8 days and 1 year in the partially adjusted model except for the 3-6 month period but in the fully adjusted model it was only predictive between 8 and 14 days. Plans to quit was predictive of relapse beyond one month and up to 1 year of quitting in the partially adjusted model with that effect increasing over time quit intervals but was no longer predictive in the fully adjusted model once other predictors were controlled for.

Number of friends smoking, a measure of social influence, predicted relapse that occurred beyond 2 weeks up to 6 months and again in the 1-2 year period but was predictive throughout the first two years in the fully adjusted model with the effect appearing to peak at the 3-6 month time interval (significant by-time quit interval interaction).



Unlike the aforementioned measures, self-efficacy was protective against relapse in the first 3 months of quitting with the effect diminishing in the partially adjusted model but remained constant in the fully adjusted model.

Reported use of any stop-smoking medication for the attempt was protective against relapse in the first 2 weeks of quitting, and then it became predictive of relapse from 1-6 months with similar pattern for both partially and fully adjusted models (interaction with time quit, both significant).

As a sensitivity analysis, we repeated the fully adjusted analysis without the wanting to quit variable (asked from Wave 3 onwards) in the model. The only noticeable difference in results (see Table S1) was that the significant effects of the two measures of smoking functional value were no longer evident indicating some complex interactive effects with the wanting to quit measure. Further analyses revealed that the effects of enjoyment and important part of life measures on relapse and how they varied over time quit were moderated by wanting to quit, dichotomized into “a lot” versus “other” (enjoyment x time quit x want to quit interaction significant at  $p=.054$  and important x time quit x want to quit interaction significant at  $p=.038$ ). As shown in Table S2, the predictive effect of enjoyment belief, both its strength and trend over time, was attenuated when wanting to quit was strong. Important part of life belief was predictive of relapse in the 1 to 2 years quit period but only for the group who expressed a strong wanting to quit. However, this belief was protective against relapse that occurred beyond 2 years but only for the group without a strong wanting to quit. In addition, we also explored the sociodemographic effects and found older age was protective against relapse starting around 1 month while higher income and education were protective in the early weeks and months of quitting with gender having no effect at all (see Table S3).

## DISCUSSION

This study shows that a wide variety of theorized determinants of smoking relapse have time-varying relationships with relapse, suggesting that their roles in maintaining smoking abstinence change over time. It confirms the findings of Yong et al (18) and shows that measures of nicotine dependence such as HSI and its two component measures (CPD and TTFC) lost their potency as determinants of relapse after around 1-3 months. The present study found HSI to be predictive of relapse up to 3 months, rather than the one month of abstinence in Yong et al (18). Cigarettes per day showed similar pattern of prediction, being predictive up to 3 months but time to first cigarette was less predictive than before, becoming non-predictive after 1 week post quitting. The slight disparity in findings may have been due to a combination of the larger sample size, controlling for a

range of other predictors and the use of alternate version of the HSI in the present study. The minor differences notwithstanding, it is clear that these measures only capture aspects of dependence relating to habit strength and not those related to the chronic relapsing nature of smoking, unlike reported strong urges to smoke post quit which have been shown to be predictive of long-term relapse (17). This brings into question the use of the HSI as a general measure of dependence.

As expected and consistent with past research (18), use of stop-smoking medications during quit attempts was protective in the early weeks of quitting but once people stop using them, some of the risk returns. In other words, when medications are in use, they mask the effects of some risk factors for relapse (e.g., factors that generate cravings) but because these underlying factors remain, people are more vulnerable to relapse when they stop the medications. Given that the increased relapse is far smaller than the early protective effect, it suggests that only some of the benefit has been lost. It may be that longer use of medications would allow for further reduction in the underlying determinants. If so, some smokers may benefit from using stop-smoking medications longer term (23). The protective effect of higher socioeconomic status in the first weeks of quitting may reflect greater resources and support available to those from advantaged background during this period (24) but whatever it is, it does not persist. There was no effect for age in the early period, but beyond 1-month post quit, older quitters were less likely to relapse, perhaps a function of extra motivation due to experiences of the negative health impact of smoking (25) or of perceived improvements in short-term functioning, thus, increasing their motivation to quit for good (26).

Interestingly, motivational factors, both smoking (i.e., enjoyment and important part of life) and quitting related ones (i.e., premature butting out of cigarettes, past failed quit attempts, wanting to quit and plans to quit) were all positively related to relapse with little evidence of interactions with time quit, particularly when the effects of other predictor variables were taken into consideration. The finding that the measures of motivation to quit predict relapse is consistent with other findings (1, 3), and has been interpreted to be because those highly motivated who were still smoking may be people with greater than normal difficulty in maintaining abstinence. That these effects largely persisted in the face of other measures of dependence suggests they are picking up something that these other measures are not able to. Of interest is the complex interactive effect found between the two measures of smoking functional value and desire to quit whereby the positive predictive effect of enjoyment belief and the unexpected protective effect of perceiving smoking as an important part of life became weakened in the context of a strong desire to quit. These findings suggest that once people have resolved to quit, they can counteract any positive value they hold about smoking and even to the extent of it having a protective effect on relapse.

Consistent with past research (6), quitting self-efficacy, a measure of capacity/task difficulty, showed a protective effect on relapse but was only predictive up to 6-month post quit

with similar strength of association suggesting that pre-quit measure of self-efficacy is only useful for predicting relapse in the first six month of quitting. This is not surprising given that past research suggests that both the stable and dynamic components of quitting self-efficacy are important determinants of relapse (6, 17, 27), the latter being a function of the experiences of the task difficulty post quit.

Evidence of number of friends who smoke being predictive of relapse up to 2 years of abstinence suggests that social influence may have a more enduring effect on relapse than other determinants of relapse, which is consistent with the idea that a stable non-smoking lifestyle takes time, especially when others in their social circle are still smoking. Consistent with past research (7, 17), number of friends who smoke have less of an influence on relapse in the early weeks of quitting when people are focusing on quitting and may make extra efforts to avoid smoking friends but over time as priority shifts, people may not be able to keep this up making them more vulnerable to relapse.

The findings of this study are consistent with models that suggest a shift in the determinants of relapse within months of quitting. More research is needed to see if markers of any abrupt transitions can be found or whether this is a more gradual transformation. The time-sensitive nature of the effects found may help explain why current efforts to prevent long-term relapse have not been very successful, as they may have been targeting potential influences at the wrong times, or at least not warning quitters of how the risks may change. In the early periods of quitting, highly dependent smokers and those who hold strong functional beliefs about smoking are at greater risk of relapse and may benefit from intervention that boosts their self-confidence in quitting. They might also be encouraged to use stop-smoking medications to help them cope better with withdrawal symptoms. Those who have managed to survive a month, especially those with a history of past failures, may need help to transition from a period when quitting is a focal activity, to one where vigilance and the ability to reengage when needed may be more important. Finally, for those with lots of smoking friends, they need to be aware of the persisting risk, and unless they are prepared to shift friendship group towards non-smokers, they will need ongoing strategies to resist the inevitable temptations others smoking brings.

### Strengths and limitations

The study strengths include prospective cohort design, large sample size, data from multiple countries and a comprehensive set of key known predictors of relapse. However, several study limitations warrant discussion. First, our findings were based on self-report data which may be affected by recall and social desirability biases. This is most likely a problem for short quit attempts given our rather long interwave intervals, so more caution should be exercised in interpreting the

findings of relapse within the first week (28). Second, only pre-quit predictor variables were analyzed and as some of them are known to change over time quit (22), the effects of those factors are likely to be underestimated, particularly for longer term outcomes. Self-efficacy is the most notable case here. Future research should endeavor to measure them (where possible) over the course of the attempt to assess the dynamic elements of the predictors. Third, risk estimates for longer term relapse are less reliable as they are based on smaller samples. Fourth, given drop-out rate was higher in the later time quit intervals, risk could be underestimated if those having relapsed were more likely to drop out. Fifth, social influence dimension is not well captured as the number of friends smoking variable may be confounded with general social support. Lastly, only one quit attempt per individual over the study period was coded for analyses. However, the findings are likely to be robust to effects of past quitting given our fully adjusted results were based on models which controlled for reported past year failed quit attempts. Beyond this, failed attempts are poorly reported (28).

## Conclusions

This study provides evidence to support the notion that some determinants of relapse vary over the duration of abstinence suggesting that their relative importance in influencing relapse changes across the different stages of quitting and underscore the need for some level of a time-based approach to relapse prevention. In particular, the findings that measures of dependence used here typically only predicted in the early months mean these measures would seem insensitive to the chronic relapsing aspect of dependence. These measures may be better thought of as measures of habit strength, rather than as comprehensive measures of dependence. The implications of these findings for relapse prevention will only become clear once research identifies which of these factors play likely causal roles in increasing relapse susceptibility.

## Acknowledgements

Ethics approval for the study was obtained from the relevant institutional Ethic Committees at the University of Waterloo, the Cancer Council Victoria, Australia and King's College London, UK. The ITC Four Country Survey was supported by multiple grants from the US National Cancer Institute including R01 CA100362 and P50 CA111236 and also in part from grant P01 CA138389 and P01 CA200512 (Medical University of South Carolina, Charleston, South Carolina). Additional grant support was provided by the Canadian Institutes of Health Research (79551, 115016), and National Health and Medical Research Council of Australia (1005922, 1106451).

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